

Developing A Center For Comparative Effectiveness Information

High-level consideration of a new U.S. entity to assist in developing evidence for decision making based on effectiveness.

by **Gail R. Wilensky**

ABSTRACT: Interest in objective, credible comparative clinical effectiveness information has been growing in the United States, both by those who support competitive behavior in health care and by those who support administered pricing. The Medicare drug benefit has heightened interest in better information, although the potential payoff is even greater for medical procedures than for drugs, since procedures account for more of the health care dollar. Careful consideration needs to be given regarding the appropriate structure, placement, financing, and function of an agency devoted to comparative effectiveness if it is to achieve its objective: a mechanism to support better decision making in health care. [*Health Affairs* 25 (2006): w572–w585 (published online 7 November 2006; 10.1377/hlthaff.25.w572)]

AMONG THE MANY CONTROVERSIAL FEATURES of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, none has caused more dissension than the provision stating that the secretary of health and human services (HHS) “may not interfere” in the negotiations between drug manufacturers and plans regarding prices or formularies. With the full drug benefit just being implemented, it is far too early to know whether this provision will be able to withstand the inevitable future pressures to rein in Medicare Part D spending. The prohibition on government from using administered pricing or the full weight of Medicare’s purchasing power to drive down prescription drug prices in the context of the new drug benefit has renewed interest in having better information available on the relative clinical effectiveness and cost-effectiveness of alternative therapeutic treatments as a strategy to moderate spending. What has been particularly promising, at a political level, is that interest in clinical effectiveness data is present both among those who support administered pricing and among those who oppose it.

Interest in better comparative information is not new.¹ Indeed, it seems to in-

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crease whenever there is renewed interest in competitive behavior in health care. But interest in objective, credible comparative effectiveness information has not been limited to those with free-market interests. Several European Union (EU) health systems rely on comparative effectiveness information in their decision making regarding drug coverage.²

Most of the interest in comparative effectiveness information has focused on pharmaceuticals, although it has sometimes been directed toward device coverage decisions as well. This focus on pharmaceuticals has also occurred in the United States, probably because the larger share of out-of-pocket spending has produced a greater public awareness of spending on drugs, although it might also be because there is greater uniformity among drugs than among other health services.

Although drugs and medical devices are important areas of health care, they are not the only areas that could benefit from comparative effectiveness information. In fact, since drug spending accounts for only about ten cents of each health care dollar, the potential payoff for better decision making is even greater in other areas of health care, particularly medical procedures. But because of the relatively rapid rise in prescription drug spending earlier in the decade and the political “third rail” that pharmaceutical manufacturers have long represented, the interest in good comparative data is especially strong for prescription drugs.

Finding mechanisms that will help the United States make better coverage and spending decisions is critical. The United States spends far more per capita than other developed countries: It spent \$5,267 per capita in 2002, compared with only \$3,446 per capita in the next-highest-spending country, Switzerland.³ There are many reasons that explain the higher U.S. levels of spending, such as higher incomes and greater system capacity. However, the increased spending does not appear to be producing uniformly better outcomes than other countries experience. More importantly, the long-term U.S. spending growth on health care will present many challenges if it continues indefinitely. On average, spending on health care has increased about 2.5 percent faster than the economy. If this growth rate were to continue until 2045, the federal share of spending on health care would claim the same share of the economy as the total federal budget today (not counting payments on interest on the national debt). Finding politically acceptable ways to reduce the long-term growth rate in health care spending will be difficult. Within this context, learning how to “spend smarter,” rather than relying on arbitrary mechanisms to limit spending, begins to look very appealing.

The focus of this paper is to assess the various options regarding the structure, placement, financing, and functions of an agency devoted to comparative (clinical) effectiveness assessment. Pros and cons of the major options are presented, along with a judgment about which strategies would be most likely to be acceptable to the most important stakeholders. A brief discussion of how other countries have handled decisions about the placement and financing of comparative effectiveness centers is also included.

Current Practice/Current Law

Under current law, drugs and devices need to obtain approval from the Food and Drug Administration (FDA) with regard to safety and efficacy before they can be marketed. Although data from clinical trials serve the needs of the FDA approval process, they generally do not provide information that is useful for comparative effectiveness purposes. FDA clinical trials typically focus on efficacy relative to placebo, whereas analyses of comparative effectiveness would require information on the relevant alternatives to the new therapy, device, or procedure.

■ **Private-sector efforts.** Private-sector entities have attempted to assess comparative clinical effectiveness as part of their coverage decision processes. One of the pioneers is the Technology Evaluation Center (TEC) established by the Blue Cross Blue Shield Association (BCBSA) in 1985. Its technology assessments rely on comprehensive reviews of existing clinical evidence and focus on the clinical effectiveness and appropriateness of a specific medical procedure, device, or drug. Its clients include other private-sector payers as well as the Centers for Medicare and Medicaid Services (CMS), although the CMS is prohibited by law from making coverage decisions based on drugs' or devices' relative effectiveness.

Health plans and hospitals have implicitly performed such assessments as part of their formulary deliberations, although they have been criticized for using procedures that lack transparency and rigor. The multipayer U.S. system has probably contributed to slower growth in the use of formularies compared with single-payer countries, although formularies have now become an important part of the pharmaceutical benefit management (PBM) industry. Late in the 1990s, Regence BlueShield (Seattle) began asking pharmaceutical companies to submit standardized packages of clinical and economic evidence as part of their formulary design deliberations.⁴ The Academy of Managed Care Pharmacy (AMCP) has endorsed a set of guidelines for providing similar information and has encouraged health plans to use its guidelines. Unlike the clinical information associated with FDA studies, these guidelines provide detailed information on a drug's economic value relative to alternative therapies, in addition to the drug's safety and efficacy. According to a 2003 Bruckner Group survey, managed care organizations, representing approximately 65 percent of covered lives, had "officially adopted" the AMCP guidelines, and "nearly all players" were using them "to some extent."⁵

■ **Public-sector efforts.** Several federal agencies are also involved to some degree in promoting or assessing clinical effectiveness, although most of them rely on systematic reviews of existing research rather than funding new prospective studies of comparative effectiveness. The agency that has been specifically directed to address issues of comparative effectiveness as part of MMA is the Agency for Healthcare Research and Quality (AHRQ). AHRQ is the only federal agency whose primary mission is both to support and to conduct health services research, including comparative effectiveness, although it is not the only agency that does health services research. AcademyHealth, the professional association of health services research-

ers, recently estimated that AHRQ accounted for only a little more than 20 percent of the \$1.5 billion in federal funds spent for health services research.⁶ The agency with the largest health services research spending is thought to be the National Institutes of Health (NIH), although its funds for health services research represent only a small fraction of its budget.⁷

Section 1013 of MMA authorized \$50 million and appropriated \$15 million in fiscal year 2004 for AHRQ to conduct research and set priorities relating to improving outcomes as well as the clinical effectiveness and appropriateness of health services, including prescription drugs. There is no provision for the use of cost-effectiveness information in MMA, which presumably reflects continued sensitivity to the use of that type of analysis in Medicare's decision making. The law also requires that the secretary of HHS establish an initial list of priorities, complete the evaluation of the initial priorities, and disseminate the research findings within eighteen months, and then develop strategies. Thus, in existing law, AHRQ is clearly envisioned as the site of future research and funding for a center of comparative effectiveness information. However, many questions remain as to whether AHRQ would be the best placement for this effort, and what the alternatives would be. I now turn to an examination of other countries' experiences, in an effort to assist U.S. policymakers in their deliberations.

Experiences In Other Countries

Many countries have centralized the process for performing comparative clinical and economic assessments. These agencies typically exist as part of their governments, which is not surprising, since these are all countries with centralized payer systems. They do differ in important respects, however, particularly with regard to the mandatory nature of the guidelines.

■ **Australia.** Australia was an early adopter of cost-effectiveness as a requirement for a drug's inclusion on the national formulary. At some level, there has been centralized review since the Pharmaceutical Benefits Scheme (PBS) was first established in the 1950s and, with it, the Pharmaceutical Benefits Advisory Committee (PBAC). The health minister is directly responsible for coverage decisions but cannot list a drug without a positive recommendation from the PBAC. A separate organization negotiates the listing price with the manufacturer. There is no formal process for appeal. The final decision is made public, but not the rationale for the decision or the relevant clinical or cost-effectiveness data.⁸

■ **United Kingdom.** The U.K. National Institute for Health and Clinical Excellence (NICE) initiates and conducts its own evaluations, unlike in Australia, where the government body reviews and interprets the data and economic analyses submitted by the drug companies. NICE reviews all types of medical technologies, including drugs, that are likely to have a sizable health or budgetary impact or otherwise to be controversial. The actual evaluation and assessment of the technology is done by a technical committee called the Technology Appraisal Committee (TAC),

which includes a large group of academic experts, clinicians, patient advocates, and industry representatives. An academic group does the actual assessment; the TAC reviews it and publishes a recommendation, which can be appealed. The recommendation is then submitted to NICE. The NICE appraisal process has been estimated to take a year or more. NICE is not bound by the TAC's recommendations; however, drugs recommended by NICE are required to be funded by the government.⁹

■ **Canada.** Canada only recently (2003) introduced a coordinated process for reviewing drug coverage applications, the Common Drug Review (CDR). The CDR reviews only new chemical entities and new combination products, unlike NICE, which reviews some existing entities under limited circumstances. The reviews, which are not binding, are done for government drug plans in all provinces other than Quebec. An advisory committee of experts, appointed by the deputy ministers of health from each province, makes recommendations to the CDR based on assessments by reviewers, who can be either internal or external to the CDR. The advisory committee sends the initial recommendation to the manufacturer, which can appeal the decision. A summary of the recommendation and the rationale is posted, although neither the data nor the assessment is made public.¹⁰

■ **Germany.** Germany adopted a different model in 2003 when it established its Institute for Quality and Efficiency (IQWiG). The Federal Joint Committee that administers health services in Germany established the institute, which is federally funded but governed by a private foundation. The institute's governance structure involves a twelve-member foundation board, a five-member board of directors, and a thirty-member board of trustees that is reflective of its stakeholders, which acts as an advisory committee. The board also has a scientific advisory board comprising up to a dozen members. The institute is responsible for evaluating the use, quality, and efficiency of drugs and services in Germany and also evaluates clinical practice guidelines for the epidemiologically most important diseases.¹¹

The Federal Institute for Drugs and Medical Devices (BfArM) is responsible for authorizing pharmaceuticals, but authorizing them doesn't necessarily mean having them reimbursed by the statutory health insurance companies. That depends on the decision taken by the Federal Joint Committee after evaluating reports by the IQWiG. The evidence usually requires data from randomized controlled trials and a demonstrated impact of patient-relevant outcomes. The committee defines uniform pharmaceutical reimbursement for agents with similar effects—that is, within the same reference class.

Function, Placement, And Financing Options

The U.S. reliance on a multipayer health system makes the function, placement, and financing of a center for comparative effectiveness more complex, at least politically, than in the preceding countries. Unless all major payers regard the placement and financing of such a center as being consistent with the production of objective and unbiased data, the information it produces will be of little use.

The primary function of this center would be to provide an independent assessment of the comparative effectiveness of alternative therapies and procedures for use by various payers and to provide supporting information so that both patients and providers can improve their decision making. Unlike the work being done by NICE or centers in other countries, or by the BCBSA and other private-sector U.S. organizations, this center would fund prospective trials on key questions for which comparative effectiveness evidence was found missing, in addition to funding systematic reviews of existing research. This feature also distinguishes it from the work being done by AHRQ, which primarily involves systematic reviews done by its funded Evidence-based Practice Centers (EPCs) and retrospective analysis of administrative electronic health record (EHR) data. The review of existing research is an important function for the various private-sector organizations to continue doing. However, it is the production of new information, done in house by the center or by contract with various academic or clinical institutions, and the assembly and availability of known information about comparative effectiveness that will be the focus of the center being envisioned.

The placement of such a center should be judged by whether the data produced will be perceived as objective and credible, represent minimal or no conflict of interest, and be perceived as being insulated from stakeholder pressures. Financing options should be judged primarily in terms of financial sustainability and stability and, perhaps to a lesser extent, equity and political acceptability.

■ **AcademyHealth report.** AcademyHealth released a report last year on the placement, coordination, and funding of health services research within the federal government, which also includes a discussion about the establishment and placement of a comparative effectiveness center.¹² This report focuses on strategies that will strengthen health services research as a field, which is not regarded as a relevant criterion for evaluating a comparative effectiveness center. It makes several recommendations, including the formation of a separate agency to serve as the lead agency for health services research (which is the function AHRQ now serves), increased funding for health services research, and increased coordination of health services research within HHS and across the federal government.

The AcademyHealth report lays out several options for the placement of a comparative effectiveness center: placing it within AHRQ; having AHRQ oversee the comparative effectiveness studies and establishing a Federally Funded Research and Development Center (FFRDC) to undertake research syntheses of comparative effectiveness findings; creating a new quasi-governmental entity for comparative effectiveness research; and reconstituting AHRQ as a quasi-governmental entity that would include comparative effectiveness research.

Although AcademyHealth does not take a position on which option is preferable, the report emphasizes the importance of maintaining a strong linkage with the lead agency for health services research and the need for the findings to be based on scientific evidence and to be shielded from political or budgetary factors.

The latter is consistent with the criteria used in this paper to judge the various placement options.¹³ The importance of improving coordination within government of health services research in general and between the lead agency for this type of research and a comparative effectiveness center seems clear and obvious.

■ **Coordination.** Linkages and coordination between AHRQ and a new comparative effectiveness center could be accomplished in a variety of ways, such as by having the center be part of AHRQ or by having a formal or informal reporting relationship between the two. Better coordination of health services research both within HHS and between HHS and the rest of the federal government is important in its own right. The creation of a comparative effectiveness center, which by its nature will involve relationships with the FDA and perhaps the National Center for Health Statistics (NCHS) as well, will only increase the importance of such coordination. FDA approval, for example, is likely to trigger consideration for a drug's inclusion in a comparative effectiveness analysis.

■ **Preserving AHRQ.** Early on, some of the informal discussions and interviews involved in the preparation of the AcademyHealth report, in which I participated as a member of the committee that prepared it, focused on the potential risk that a comparative effectiveness center separate from AHRQ could present to AHRQ's integrity and stability. Although this might well be the case if the comparative effectiveness center were of a very modest size—as, for example, if it were funded at the \$50 million level provided for comparative effectiveness research in MMA and made separate from and therefore rival to AHRQ—it seems less likely to be an issue if a separate center were funded at a more appropriate level.

A multibillion-dollar comparative effectiveness center would make it clear that the new center's purpose is to provide credible, objective information on comparative effectiveness, allowing AHRQ to maintain its role as the place of traditional health services research, including analyses that might make use of data provided by the center. The center's size would reflect the need to sponsor new research and produce new data on comparative clinical effectiveness for the many new and existing technologies that have come on the market over the past several decades. Even at a multibillion-dollar annual level, research efforts on comparative effectiveness would need to be prioritized according to some agreed-upon principles.

Four Placement Options

■ **Option 1: placement within AHRQ.** For reasons already outlined, the most obvious choice for the placement of a comparative effectiveness center is AHRQ. AHRQ, as currently configured, could be augmented by the establishment of an independent external board, along with a panel of experts to advise on research priorities and to provide oversight for the monitoring of research contracts and the dissemination of results.¹⁴ An advantage of this approach is that it would provide a mechanism for the private sector to participate in establishing a comparative effectiveness research agenda. An independent, external board might also improve the

credibility of the findings. It would make AHRQ a strong partner for other federal agencies that would be interested in such research and would also obviously increase AHRQ's prominence and visibility, an issue that is important to some researchers but not central to the current consideration.

However, the increased prominence and visibility that a comparative effectiveness function would bring to AHRQ is a disadvantage as well, both to the agency and to the concept of a comparative effectiveness center. The center's findings might anger various stakeholders affected by the findings, who, in turn, could use the political process to threaten the continued existence of the agency that produces the "threatening" material. There is also a question of whether information produced by a governmental agency will be perceived as being objective and credible. To some extent, credibility will be affected by the even-handedness with which the process is carried out—that is, whether the areas chosen for evaluation are a good reflection of disease burden, financial burden, and scientific opportunity. Informal discussions with members of medical academe suggest that they might find it difficult to regard findings produced by a governmental organization as being other than political, whether or not that is the case. The distrust would be especially strong if the governmental agency were also the payer, like the CMS; even so, there appears now to be substantial mistrust of government's motives, with questions being raised about appointments to various scientific and medically related committees. Finally, placement within AHRQ would limit opportunities for the private sector to participate in funding. This might not only take away a possible funding source but also might mean less of a commitment by the private sector to the success of such a center.

■ **Option 2: placement elsewhere within HHS, as a new or existing entity.** A second alternative is to establish a new center or board elsewhere within HHS. In principle, such an entity could also be established outside of HHS, elsewhere within the executive branch, but there is little obvious advantage to such an arrangement.

Discussions with people inside and outside of government suggest little enthusiasm for placing a comparative effectiveness center within the NIH. Although it conducts a large dollar amount of health services research in its various centers, such research is clearly not a primary focus of any of its centers, and there is little reason to believe that comparative effectiveness would be regarded as comparable in importance to other NIH center activities. The NIH, however, has enjoyed a reputation as being highly objective; to the extent that this spilled over to work on comparative effectiveness, it would make the NIH attractive as a site.

Another alternative is to establish a moderate-size board (five to fifteen members) within HHS, or else an entirely new agency within HHS, that would be responsible for comparative effectiveness information. One advantage of a new entity is that it could be created on the model of the Federal Reserve Board—with commissioners or members having fixed, multiyear, staggered terms. Its membership therefore would not be under the control of any one president and would be

less likely to be regarded as political. Discussions with people within the industry and also within the academic and not-for-profit worlds suggest that this concept is somewhat attractive.

It has some disadvantages as well. The most obvious is that it would require the establishment of a new entity. Placing it within government also would limit any opportunities for private-sector funding, which would affect both the potential funding and, possibly, the private sector's commitment to the center. The independence of the board might lessen suspicions associated with the center's findings, although the information produced would still be associated with a government entity. To the extent that such an association results in distrust, it might still be present in this altered format. Alternatively, the more separate the entity is in government, the easier it is to target for pressure. Given prior experiences in health services research in particular, any entity that is part of government is likely to be hugely pressured by industry.

■ **Option 3: placement within a quasi-governmental entity.** A variety of quasi-governmental structures could house a comparative effectiveness center. The Institute of Medicine (IOM) is frequently thought of when the term “quasi-governmental structure” is mentioned, but there are a variety of other models to consider as well. Among two particularly interesting models, in part because they tend to be more closely associated with federal agencies, are Federally Funded Research and Development Centers (FFRDCs) and Public Foundations.

IOM/NRC. The IOM, either by itself or in conjunction with the National Research Council (NRC), is one obvious model; in fact, the IOM has expressed a willingness to serve as a clearinghouse for comparative effectiveness information and has created a senior-level Roundtable on Evidence-based Medicine to issues and feasibility.¹⁵ A rationale for adding the NRC is that having engineering assistance would be desirable and also that it would avoid any appearance of having the entity responsible for comparative effectiveness oversight being captive to the physician community.

A primary advantage of having the IOM serve this function is that it would provide for a trusted and independent intermediary to supervise the use of funds as well as the reporting and translation functions while making use of existing capacity in government for research contract management. In addition, the IOM has generally been highly regarded by both industry and government, and it might also be able to generate private funds, from industry and foundations.

Several disadvantages could be associated with housing this activity in the IOM. There is some question as to whether the IOM can act in a timely way. Although the IOM has produced several reports within a matter of months, mostly on very narrow and focused topics, its consensus process can be cumbersome.¹⁶ There is also a question of whether all administrations would be equally comfortable having this function housed in the IOM. Finally, it is unclear whether Congress would be willing to fund most of the cost of this enterprise if it were not

housed directly in government, in part because clear accountability is lacking when an activity is housed outside of government. This is not now an issue for the IOM because it is mostly funded on a project basis, albeit heavily by government, which provides its own type of accountability.

FFRDC. A different type of quasi-governmental entity that circumvents some of the issues raised by the IOM model is the FFRDC. FFRDCs are generally linked to a federal agency; in this case, the most obvious would be AHRQ. AHRQ would commission new research on comparative effectiveness. The FFRDC would synthesize existing research, including the newly generated research resulting from AHRQ contracts; could make recommendations and assessments concerning the findings; and could determine how the findings would be disseminated.

FFRDCs usually receive most of their funding from federal agencies and need to be sponsored by an executive-branch agency, which monitors their funds. They typically operate as private, not-for-profit organizations and by law can only accept 30 percent of their funding from private sources, although depending on the size of the FFRDC, 30 percent could represent a sizable contribution from the private sector.

There are several advantages to the FFRDC model. FFRDCs clearly involve the private sector and therefore could provide some additional private buy-in. They also allow the private sector to finance work on comparative effectiveness. At the same time, they are directly linked to the federal government, which might be important if the government is assumed to be providing most of the funding.

Some of the disadvantages of FFRDCs are those associated with the uncertainties of a mechanism that is used only occasionally and under limited circumstances. Supposedly they are only used when they are associated with work that cannot be accomplished by existing government or contractor resources. It is also unclear whether the private sector would be assured that the research being commissioned by the federal agency was without political influence and, in general, whether there is enough arm's-length distance between the FFRDC and its agency sponsor to provide assurance of objectivity.

The FFRDC linked to AHRQ represents an interesting compromise between maintaining the comparative effective function in government and the use of a more independent type of quasi-government entity, such as the IOM. However, to the extent that the FFRDC and AHRQ were viewed as being too closely related, one could imagine this combination representing the worst of all worlds: complications of a separate organization responsible for some of the comparative effectiveness activities, suspicions about the independence and credibility of the material produced, and increased exposure and potential threats to AHRQ.

Public Foundation. An alternative to the FFRDC model is the Public Foundation (PF). PFs are not-for-profit organizations that act as a type of public charity. Their primary purpose is to make grants. Part of the requirement for being established as a public charity and for receiving tax-exempt status from the Internal Revenue

Service (IRS) is that PFs have to seek money from diverse sources, and at least one-third of their money has to be from the general public. Also, unlike FFRDCs, PFs can act completely independently from their parent organizations. In contrast to FFRDCs, which are more limited in scope and supposedly restricted to work that cannot be done by existing government agencies or contractor resources, PFs usually have broader missions.¹⁷

The advantages and disadvantages of PFs in general are the same as for the FFRDC, but the PF seems a slightly less relevant model. FFRDCs are more likely to be associated with research, such as the National Defense Research Institute, which is part of RAND. PFs have been used by the Centers for Disease Control and Prevention (CDC) and the NIH, but they are mostly used to raise money and make grants to other institutions.

■ **Option 4: placement within the private sector.** Maintaining the comparative effectiveness center function within HHS or elsewhere in the executive branch represents one extreme. Locating such a center within the private sector represents the other. In principle, a comparative effectiveness center could be a freestanding institution or one affiliated with a university or other entity. Presumably, it would be a not-for-profit institution, committed to following certain federal guidelines regarding transparency and availability of data.

The advantage of locating the center in the private sector is that this would minimize any concern that the outcomes reflected political pressure from the government. It would not be subject to any of the personnel or contract constraints of government and would provide maximum opportunities for private-sector participation, in both funding and substantive involvement.

There are also a variety of disadvantages to this approach. Perhaps the most serious is that the government might be unwilling to be the primary funder if the center were located in the private sector because of concerns about control and accountability. A second, potentially serious disadvantage is that the lack of government involvement or oversight might raise questions about the objectivity of the findings and leave the center subject to charges of being captured by industry. This concern might be alleviated by the use of an external board of government and academic experts providing governance to the center. A related disadvantage involves issues of transparency and whether it would be possible to require the same level of transparency in a private-sector activity as in a governmental or quasi-governmental activity and whether, without transparency, the findings would be regarded as objective.

The notion of a comparative effectiveness center in the private sector has not been regarded as a serious option to date, probably because the complete removal of government would raise too many questions regarding objectivity or capture by industry. It is not surprising that government or academe would not find this type of structure interesting, but it is surprising that there does not seem to be strong support in industry, either.

Financing A Comparative Effectiveness Center

The most obvious and direct way to finance at least the public portion of a comparative effectiveness center is through a direct appropriation by Congress. The rationale for public funding is that information is a public good, in the most classic sense: that is, it is not excludable and nonrival in its consumption. Economic theory argues that goods or services that meet this definition will be underproduced by the private sector and should therefore be financed by government.

The theoretical argument for traditional public financing of a comparative effectiveness center seems clear enough. However, the vagaries of relying on an adequate annual appropriation suggest that a different financing mechanism might be preferable. The most frequently considered alternative is financing by the Medicare Trust Funds. This would present a potentially more stable funding source, since it would not be subject to annual review, but it is difficult to imagine political agreement on this approach in the current political environment. However, it might be possible to rely on the Medicare Trust Funds to finance a portion of the costs, since Medicare would obviously be an important beneficiary and could allow decision making about reimbursement that could result in future Medicare savings. This, of course, assumes that Medicare would be empowered to use comparative effectiveness as one of the criteria in setting reimbursement, although now that private-sector entities are administering the Part D drug benefit, better information on comparative effectiveness could produce savings even without additional authority being granted.

The private sector might also be willing to underwrite some of the costs. One option is to rely on voluntary contributions, although since information can be regarded as a public good, economic theory suggests that this is not likely to succeed. One of the attributes of a public good is that once the good or service—or in this case, the information—is available, it will or should be available to all without charge. However, that encourages “free riders.”

A small charge or fee could be assessed on all users, providers, or suppliers of health care services or on health plans. This charge should be broadly based, rather than limited to one sector or a portion of the payers and definitely not limited to a small sector like pharmaceuticals or devices. A user-fee system of financing has supplemented FDA funding and helped reduce the time required for the approval process; this could be regarded as a precedent for partial funding of a center on comparative effectiveness. In sum, while the preferred financing is general-fund financing, it is possible to imagine a combined funding strategy that would be less susceptible to the vagaries of the appropriations process.

Concluding Comments

Better information about the comparative effectiveness of various medical strategies and procedures might not, in itself, lead to better decision making in health care unless there is also a major change in financial incentives. However,

better information is an important component of such an outcome. Most countries have limited their focus in comparative effectiveness information to drugs and medical devices, but since the majority of health care spending occurs for medical and surgical procedures, these areas also must be included in the design of a comparative effectiveness center.

Other countries that have established cost- or clinical effectiveness as a requirement for coverage or reimbursement, or both, have centralized the process. Countries differ in terms of whether the recommendations that come out of such groups are mandatory or advisory, the transparency of the process, and whether the results are subject to appeal. The appropriate function, structure, placement, and financing of a comparative effectiveness center in the United States will need to reflect this country's political sensitivities and the unique public/private structure that has developed here. The function of a comparative effectiveness center in the United States would be to provide credible, objective information on the comparative effectiveness of alternative therapies and technologies, not to make centralized coverage decisions. The information would be available to any payer and also could be used for better decision making by patients and providers. To date, the United States has been unwilling to include statutory language that would allow cost-effectiveness information to be used in making coverage decisions even in large public programs such as Medicare, nor has there been any inclination to make all payers use the same coverage or reimbursement decisions. Although continued increases in health care spending that are much greater than the economy's growth could change this history, it does not appear likely anytime soon.

The obvious choices of where to place a comparative effectiveness center are to locate it in HHS, either as a part of AHRQ, which already carries out some of these functions although to a rather limited extent, or elsewhere in the department. Alternatively, a variety of quasi-governmental or even private-sector options are possible. On balance, the placement of a comparative effectiveness center within a quasi-governmental entity seems the most attractive. The idea of establishing an FFRDC, perhaps linked to AHRQ or to a newly established board in HHS, is intriguing. FFRDCs are still relatively unknown, particularly in the health services research world, and more attention would need to be given to their administrative complexities or limitations to their use. The notion of attaching the FFRDC to a new board within HHS, which had a membership appointed in staggered terms, is also very appealing, although its appeal would have to be weighed against the advantage of linking to AHRQ, which could be generating some of the research needed by the FFRDC.

If the FFRDC model proved too complex or an otherwise undesirable administrative entity, more exploration of the IOM, particularly paired with the NRC, should be undertaken. Some believe that the IOM is too cumbersome, largely because of its review process, but it has shown itself to be capable of being time-sensitive in at least some circumstances. Having a new entity that reports to the

IOM but is not of the IOM/NRC, per se, might allay some of these concerns.

Despite many different views, there is widespread agreement on the attributes that need to be associated with a comparative effectiveness center: objectivity in the selection of what is studied, credibility in the findings, and independence—from political pressures generated either by government or by private-sector stakeholders. How best to achieve this set of outcomes, not surprisingly, differs in the eyes of different beholders.

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NOTES

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16. Examples of quick-turnaround reports from the IOM include the following: (1) Vaccinations and Sudden Unexpected Death in Infancy—meeting date: 28–29 October 2002, release date: 6 October 2003; (2) Vaccine and Autism—meeting date: 9 February 2004, release date: 17 May 2004; and (3) Review of the HIVNET 012 Perinatal HIV Prevention Study—meeting date: September 2004, release date: 7 April 2005, Sponsor: NIH.
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